PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CRITTENDEN	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/AU2004/001341	International filing date *(day/month/year)* 30 September 2004	Priority date *(day/month/year)* 1 October 2003

International Patent Classification (IPC) or national classification and IPC

Int. Cl.

A61K 35/74 (2006.01) ***A61K 47/26*** (2006.01) ***A61K 47/42*** (2006.01)

Applicant

COMMONWEALTH SCIENTIFIC & INDUSTRIAL RESEARCH ORGANISATION et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24 November 2004	13 January 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **S. Chew** Telephone No. (02) 6283 2248

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001341

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

[X] The international application in the language in which it was filed

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (under Rules 12.3(a) and 23.1 (b))

[ ] publication of the international application (under Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

[X] the international application as originally filed/furnished

[ ] the description:

pages as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] the drawings:

pages as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**YES**
	Claims **1-15**	**NO**
Inventive step (IS)	Claims	**YES**
	Claims **1-15**	**NO**
Industrial applicability (IA)	Claims **1-15**	**YES**
	Claims	**NO**

2. Citations and explanations (Rule 70.7)

This report has considered the following documents cited in the International Search Report:

D1. WO 2003/026687 A1 (Nutraceutix Inc) 3 April 2003

D2. WO 2003/010299 A1 (Alimentary Health Limited) 6 February 2003

D3. WO 2003/010297 A1 (Alimentary Health Limited) 6 February 2003

D4. US 2003/0152629 A1 (Shefer A et al) 14 August 2003

D5. WO 1999/017788 A1 (Abbott Laboratories) 15 April 1999

D6. EP 0904784 A1 (NV Nutricia) 31 March 1999

D7. WO 2001/085774 A1 (Alimentary Health Limited) 15 November 2001

Novelty (N): Claims 1-15

Claims 1-15 are directed to an encapsulated probiotic wherein the probiotic is dispersed in

(a) an aqueous suspension of a protein and a carbohydrate

(b) an oil in water emulsion of a film forming protein and a carbohydrate and a fat, or

(c) an oil which is subsequently dispersed in a film forming protein and a carbohydrate

D1 has disclosed a controlled release delivery system comprising a biological component (such as a probiotic). Various embodiments also include hydrophilic agents (such as a protein selected from the group consisting of gelatin or casein) or hydrophobic agents, a release-modifying agent (such as polysaccharide which may include gelatin) and/or an electrolyte. (See pg 4, ln 20-33; pg 5, ln 11-26; pg 9, ln. 14-19, pg 10, ln 5-34; pg 12, ln 23-pg 13, ln 24).

D2 has disclosed at least one *Lactobacillus* strain which may be combined with a prebiotic (such as glucose) and an ingestible carrier (such as a milk product) in the form of a capsule or tablet. One embodiment discloses the addition of a peptide and/or protein, a lipid, a carbohydrate, a vitamin, mineral and/or trace element for use in the treatment of inflammatory bowel disease or irritable bowel syndrome. (See pg 3, ln 6-23; pg 7, ln 10-16; claims).

D3 has disclosed at least one *Bifidobacterium* strain which can be included with a prebiotic and an ingestible carrier (such as a milk product) in the form of a capsule or tablet. One embodiment discloses the addition of a peptide and/or protein, a lipid, a carbohydrate, a vitamin, mineral and/or trace element for use in the treatment of inflammatory bowel disease or irritable bowel syndrome. (See pg 3, ln 1-18; claims 17, 21 and 23).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: V

D4 has disclosed a controlled release delivery system comprising one or more active ingredients (such as *Lactobacillus*), flavours (such as sugar, protein, dairy products), sensory markers encapsulated in a moisture sensitive microsphere (comprising material such as polysaccharides). (See para [0046]; [0056]-[0068]; [0080]- [0083]; [0100]; [0106]; claims 1, 13 and 23).

D5 has disclosed at least one probiotic (such as selected *Lactobacillus* and *Bifidobacterium* strains) that can be encapsulated for the treatment of candidiasis. A preferred embodiment discloses the addition of proteins, carbohydrates, vitamins, minerals, trace elements and the like. (See pg 7, ln 5-8; pg 8, ln1-3; pg 12, ln 10-31; claims 10-13).

D6 has disclosed a composition containing probiotic micro-organisms (*Bifidobacterium* strain, *Enteroccoccus faecium* and the *Lactobacillus* strain) with the addition of food components and/or additives. Various embodiments disclose the composition to include prebiotics such as proteins, polysaccharides, fatty acids and growth factors obtained from milk whey or colostrum. (See col 2, ln 30-41; col 4, ln 28-29, 40-46; col 5, ln 26-col 6, ln 22; col 7, ln 14-22, 47-49; example 6; claims).

D7 has disclosed an adherence factor derived from *Lactobacillus* to improve gut function which can be encapsulated. One embodiment disclosed the addition of proteins, lipids, carbohydrates, vitamins, minerals and/or trace elements. (See pg 5, ln 10-25; claims).

D1-D7 has each disclosed all the features of claims 1-15. Therefore the claims lack novelty.

Inventive Step (IN): Claims 1-15

Claims 1-15 lack an inventive step for the reasons stated above.

Industrial Applicability (IA): Claims 1-15

Claims 1-15 are considered to be industrially applicable.